



Patent Technology Centers

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Fax Notes:

Dear Mr. Sadoff:

Re: Your Ref: 620-393
USPN: 10/551,698

Further to my telephonic voice mail messages from earlier today (i.e., 06/28/2011), enclosed for your review and discussion with you is a proposed Examiner's Amendment to the currently pending Claims in the instant Application. Said amendment has been approved by the patentability conference at USPTO.

I shall appreciate a telephone call at 571-272-0923 by no later than

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EXAMINER'S PROPOSED AMENDMENT*DRAFT*

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicants, an amendment may be filed as provided by 37 C.F.R. §1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this Examiner's amendment was given in a telephone interview on XXXXXXXXXXXXXXXX with XXXXXXXXXXXXXXXXXXXXXXXX, Applicants' Representative.

In the Claims:

Please amend the following claims in the instant application.

1. (Currently Amended) A tubular tissue growth guide comprising[.];
an inner core comprising a biopolymer matrix seeded with cells;
an outer sheath surrounding said inner core[.];
said inner core being tethered to said outer sheath only at opposing ends of said guide;
said seeded cells providing e mechanical tension in said core between the tethered opposing ends.
2. (Currently Amended) A tubular guide according to claim 1, wherein the mechanical tension in said core causes alignment of the cells.
3. (Currently Amended) A tubular guide according to claim 1, wherein the

mechanical tension in said core causes alignment of the fibres of said biopolymer matrix.

4. (Previously Presented) A tubular guide according to claim 1₂ wherein the biopolymer matrix is a collagen matrix.

5. (Currently Amended) A tubular guide according to claim 1 adapted for use as an implant in the repair of damaged tissue.

6. (Currently Amended) A tubular guide according to claim 5₂ wherein the outer sheath comprises one or more entry ports for entry of regenerating tissue.

7. (Currently Amended) A tubular guide according to claim 5 adapted for the regeneration of nerves.

8. (Currently Amended) A tubular guide according to claim 7₂ wherein the outer sheath comprises an entry port for entry of regenerating nerve and an exit port for exit of a regenerating nerve.

9. (Currently Amended) A tubular guide according to claim 8 comprising one or more fixings for fixing in place the entry point adjacent to the proximal end of a damaged nerve and the exit point at the distal end of a damaged nerve.

10. (Currently Amended) A tubular guide according to claim 5₂ wherein the mechanical tension in the core imparts traction on regenerating tissue in the guide

11. (Currently Amended) A tubular guide according to claim 1₂ wherein said seeded cells comprise one or more of Schwann cells, neural fibroblasts, fibroblasts, tenocytes, astrocytes, osteoblasts, myoblasts, melanocytes, smooth muscle cells, secretory or gland vessel cells, epithelial cells and endothelial cells.

12. (Currently Amended) A tubular guide according to claim 11, wherein said cells comprise Schwann cells and fibroblasts.

13. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath is biosorbable.

14. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath is non-porous.

15. (Currently Amended) A tubular guide according to claim 1, wherein said outer sheath is selected from the group consisting of-silicone, phosphate glass, polylactone, polyglycone, polycapryolactone, hyaluronan or derivatives thereof, collagen, fibrin, fibronectin, cellulose, chitosan, and starch.

Claim 16. (Canceled)

17. (Currently Amended) A tubular guide according to claim [[16]] 1, wherein said outer sheath is shaped to cooperatively engage the inner core at the tethered ends to prevent co-axial movement of the core relative to [[the]] said outer sheath.

18. (Currently Amended) A tubular guide according to claim 17, wherein said outer sheath comprises one or more openings which cooperatively engage the inner core at the opposing ends.

19. (Currently Amended) A tubular guide according to claim 18, wherein said openings comprise a plurality of pores.

20. (Currently Amended) A tubular guide according to claim 18, wherein said openings comprise one or more holes in [[the]] said outer sheath.

21. (Currently Amended) A tubular guide according to claim 1₂ wherein ~~[[the]]~~
said outer sheath is chemically fixed to the core at the tethered ends.

22. (Previously Presented) A guide according to claim 1 adapted for *in vitro* use
as a bioreactor for the growth of tissue.

23. (Currently Amended) A method of making a guide for tissue growth
comprising ~~[[;]]~~;
providing an outer sheath ~~[[,]]~~;
introducing cells to a liquid biopolymer matrix to produce a cell seeded
matrix ~~[[,]]~~;
introducing said cell seeded matrix to the interior of the outer sheath ~~[[,]]~~;
causing or allowing said cell seeded matrix to set; and~~[[,]]~~
fixing ~~[[the]]~~ said cell seeded matrix to ~~[[the]]~~ said outer sheath to tether
said cell seeded matrix to only the opposite ends of said outer sheath.

24. (Currently Amended) A method according to claim 23₁ wherein ~~[[the]]~~ said
outer sheath cooperatively engages ~~[[the]]~~ said cell seeded matrix at the opposing
ends of said outer sheath ~~said engagement tethering~~ preventing co-axial
movement of the core relative to ~~[[the]]~~ said outer sheath.

Claim 25. (Canceled)

26. (Currently Amended) A method of facilitating growth of tissues in a human or
animal body comprising implanting a tubular tissue growth guide of claim 1 into
a human or animal body in need of said facilitating.

27. (Currently Amended) A method according to claim 23₁ wherein the cells
comprise fibroblasts and one or more cells of said tissue.

28. (Currently Amended) A method according to claim 23₁ wherein the tissue
cells comprise fibroblasts and one or more stem cells or progenitor cells of cells

of said tissue.

29. (Currently Amended) A method of claim 26, further comprising linking ends of [[the]] said tissue growth guide to broken ends of a damaged tissue in the human or animal[.]; and[.];

allowing said tissue to regenerate through said tubular tissue growth guide.

30. (Currently Amended) A method according to claim 29, wherein the damaged tissue is a nerve.

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (571) 272-0923. The examiner can normally be reached on Monday to Thursday from 7:00 A.M. to 5:30 P.M. (Eastern Standard or Daylight Savings Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue X. Liu can be reached at (571)-272-5539 Monday through Friday 9:00 A.M. to 4:00 P.M. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding may be obtained from the Patent Application Information Retrieval (i.e., PAIR) system. Status information for the published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (i.e., EBC) at: (866)-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kailash C. Srivastava
Examiner, Art Unit 1653
(571) 272-0923